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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO.       |
|---|-------------|----------------------|-----------------------------|------------------------|
| 10/500,027  | 03/09/2005  | Jonathan M Gibbins   | 15892.2                     | 2259                   |
| 22913 7590 06/21/2007<br>WORKMAN NYDEGGER<br>(F/K/A WORKMAN NYDEGGER & SEELEY)<br>60 EAST SOUTH TEMPLE<br>1000 EAGLE GATE TOWER<br>SALT LAKE CITY, UT 84111 |             |                      | EXAMINER<br>GAMBEL, PHILLIP |                        |
|   |             |                      | ART UNIT<br>1644            | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>06/21/2007     | DELIVERY MODE<br>PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                               |                                |  |
|------------------------------|-------------------------------|--------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/500,027 | Applicant(s)<br>GIBBINS ET AL. |  |
|                              | Examiner<br>Phillip Gambel    | Art Unit<br>1644               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-36 is/are pending in the application.
- 4a) Of the above claim(s) 19-31 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 32-35 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. Applicant's amendment, filed on 06/24/04, has been entered.  
Claims 1-18 have been canceled.  
Claims 19-36 have been added.
2. Since the statutory classes of "the activation of PECAM-1" (e.g., see claims 19-31) and "a screen for activator of PECAM-1" (e.g., see claim 36) are not clear, that is, it is unclear whether these claims are drawn to methods or products and, in turn, the metes and bounds of each,  
claims 19-31 and 36 have been withdrawn from consideration at this time.

Applicant is invited to amend the claims to clearly recite the claims as methods and products, including a clear preamble, transitional phrase and body of claim. With method claims, applicant should include the appropriate ingredients and method steps to carry out the claimed methods.

Claims 32-35 are subject to Unity of Invention practice herein.

3. Restriction is required under 35 U.S.C. 121 and 372.  
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 32-35, drawn to a PECAM-1 activator which is a small molecule

Group II, claims 32-35, drawn to a PECAM-1 activator which is an antibody or an antibody derivative.

Group III, claims 32-35, drawn to a PECAM-1 activator which is an agonist.

Group IV, claims 32-35, drawn to a PECAM-1 activator which is an antagonist.

Group V, claims 32-35, drawn to a PECAM-1 activator which is a ligand.

Group VI, claims 32-35, drawn to a PECAM-1 activator which is a DNA sequence.

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Group VII, claims 32-35, drawn to a PECAM-1 activator which is a complementary DNA sequence.

Group VIII, claims 32-35, drawn to a PECAM-1 activator which is an antisense DNA sequence.

Group IX, claims 32-35, drawn to a PECAM-1 activator which is a protein sequence.

Group X, claims 32-35, drawn to a PECAM-1 activator which is a recombinant extracellular domain or domains of PECAM-1.

Group XI, claims 32-35, drawn to a PECAM-1 activator which is a catalyst.

Group XII, claims 32-35, drawn to a PECAM-1 activator which is a shear.

Group XIII, claims 32-35, drawn to a PECAM-1 activator which is an oxidative stress.

Group XIV, claims 32-35, drawn to a PECAM-1 activator which is FcεRI.

Group XV, claims 32-35, drawn to a PECAM-1 activator which is the high affinity receptor for FcεRI or an activated form of said receptor.

Group XVI, claims 32-35, drawn to a PECAM-1 activator which is a FcγRIIA.

Group XVII, claims 32-35, drawn to a PECAM-1 activator which is the low affinity receptor for FcγRIIA and an activated form of said receptor.

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5. The inventions listed as Groups I-XVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions are found to have no special technical feature that defined a contribution over the prior art of Ravetch et al. (U.S. Patent No. 5,877,396) (see entire document) and Newman (U.S. Patent No. 5,917,030).

Ravetch et al. teach that Fc receptors, including FcεRI and FcγRIIA recited in the instant claims were well known and used in compositions to the ordinary artisan at the time the invention was made (see entire document, including Background of the Invention and Detailed Description of the Invention).

Newman teaches that PECAM-1 (also known as CD31), PECAM-1 variants, antibodies thereto as well as encoding nucleic acids and antisense molecules were known at the time the invention was made (See entire document, including Detailed Description of the Preferred Embodiments).

In addition applicant is reminded concerning the inherency of prior art known products.

Also, it is noted the claims encompass intended uses. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 152 USPQ 235 (CCPA 1967); In re Otto, 136 USPQ 458, 459 (CCPA 1963). See MPEP 2111.02

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

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Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

With respect to the present recitation of the claims, the following is noted as well.

Given the lack of structure or relevant identifying characteristics of a number of the claimed "activators", the "activators" have been listed above as recited in the Markush listing of said "activators" (see claim 33) even though the metes and bounds of the listed "activators" are ill-defined and may be overlapping.

Given the current recitation of the claims, certain "activators" do not make sense or the metes and bounds are ambiguous in terms of claiming a product (e.g. shear, oxidative stress).

Given the recitation of the instant claims as they read on different products that do not recite a structure or relevant identifying characteristics,

applicant is notified that a number of the claimed "activators" would be subject to rejections under 35 USC 112, first paragraph, written description and enablement

Applicant is invited to consider amending the claims to recite those "activators" *wherein the instant disclosure provides* for a "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics

Applicant is reminded to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phillip Gambel, Ph.D., J.D.  
Primary Examiner  
Technology Center 1600  
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